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Office Action Summary

Application No.	Applicant(s)
08/892,695	Gray et al
Examiner	**Art Unit**
Karen Canella	1642

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *26-28 and 48-51* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *26-28 and 48-51* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 25, 2002 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. Claims 37 and 38 have been deleted. Submitted claims 47-50 have been renumbered according to rule 1.126 and added as claims 48-51. Claims 26-28 and 48-50 are pending and under consideration.

Claim Objections

4. Claim 51 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 51 is dependent on claim 48 which is drawn to a method relying on a probe consisting essentially of "SEQ ID NO:10". For the reasons recited in the rejection below, "consisting essentially of will be read as"comprising" for purposes of applying the prior art. Claim 51 therefore, fails to further limit the scope of claim 51. In the event that applicant is able to establish limitations for "consisting essentially of SEQ ID NO:10" that will serve to limit the probe to a specific metes and bounds which is smaller in scope than "comprising", claim 51 will encompass a genus of polynucleotide sequences which would be larger than the genus of polynucleotides of claim 48, and thus fail to limit the scope of claim 48.

5. Claim 26 is objected to because of the following informalities: the typographical error of "probeconsiting". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 recites method steps wherein a nucleic acid sample is contacted with a probe which hybridizes to a target polynucleotide sequence. It is unclear what the target polynucleotide sequence is, and how this target sequence relates to the nucleic acid sample. Amendment of the claim to substitute --- nucleic acid sample--- for "target polynucleotide" is suggested.

Claim Rejections - 35 USC § 102

7. Claims 26-28 and 48-51 are rejected under 35 U.S.C. 102(a) as being anticipated by Tanner et al (Clinical Cancer Research, 1995, Vol. 1, pp. 1455-1461) or Tanner et al (Cancer Research, Aug 1996, Vol. 56, pp. 3441-3445).

Claim 26 is drawn to a method of screening for neoplastic cells in a sample comprising contacting a nucleic acid sample from a human patient with a probe consisting essentially of a sequence of SEQ ID NO:9 wherein the probe is contacted with the sample under conditions in which the probe specifically hybridizes under stringent conditions with the target polynucleotide sequence to form a stable hybridization complex; and detecting the formation of a hybridization complex wherein an amplification of said target polynucleotide sequence indicates that said cell is a neoplastic cell. Claim 48 is drawn to a method of screening for neoplastic cells in a sample comprising contacting a nucleic acid sample from a human patient with a probe that hybridizes selectively to a target polynucleotide sequence consisting essentially of the sequence of SEQ ID NO:10, wherein the probe is contacted with the sample under conditions in which the probe

specifically hybridizes under stringent conditions with the target polynucleotide sequence to form a stable hybridization complex; and detecting the formation of a hybridization complex wherein an amplification of said target polynucleotide sequence indicates that said cell is a neoplastic cell Claims 27 and 49 embody the methods of claims 26 and 48, respectively, wherein the nucleic acid sample is from a patient with breast cancer. Claims 28 and 50 embody the methods of claims 26 and 48, respectively, wherein the nucleic acid sample is a metaphase spread or an interphase spread. Claim 51 is drawn to the method of claim 47 wherein the probe comprises SEQ ID NO:10.

The specification teaches in figure 3 that the target polynucleotide sequence comprising the genomic sequence of SEQ ID NO:9 is contained within the region of chromosome 20 spanned by the RMC20C001 probe. Tanner et al (Clin Cancer Res, 1995, Vol. 1, pp. 1455-1461, cited in a previous Office action) or Tanner et al (Cancer Research, Aug 1996, Vol. 56, pp. 3441-3445, cited in a previous Office action) disclose a method for detecting breast cancer comprising hybridization with the RMC20C001 probe, wherein the nucleic acid sample is taken from a human patient with breast cancer and wherein the nucleic acid sample is an interphase nucleus. Because these references disclose detection of genomic sequences, both instant methods directed to the detection of both strands (sense and anti-sense) of in the q13.2 region of chromosome 20 are anticipated.

Applicant has attempted to amend claims 26 and 48 to recite "consisting essentially of" as opposed to "comprising" in order to obviate the prior art rejections based on the cosmid probe RMC20C001. This has been carefully considered but not found persuasive. The specification states on page 3, lines 1-6 that the instant methods rely on probes which "consist essentially of" one or more nucleic acid probes which bind to a target nucleic acid sequence at position Flpter 0.825 on human chromosome 20.

The M.P.E.P. (2111.03) states:

> The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any,

> are excluded from the scope of the claim..... For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

The specification fails to specifically define probes "consisting essentially of" SEQ ID NO:9 and 10 in a manner that would exclude probes comprising SEQ ID NO:9 or 10. Further, claim 48 reads on probes which hybridize to a target sequence "consisting essentially of SEQ ID NO:10". The cosmid probe RMC20C001 as disclosed by Tanner et al would hybridize to a target sequence consisting essentially of SEQ ID NO:9 as well as a target sequence consisting of SEQ ID NO:10 because RMC20C001 encompasses SEQ ID NO:10.

Applicant argues that claims drawn to SEQ ID NO:10 do not overlap with the RMC20C001 probe as evidenced by Figure 3. This has been considered but not found persuasive. There is no indication of the relative locations of RMC20C001 and SEQ ID NO:10 within figure 3 or the Brief Description of figure 3 on pages 12-13 of the specification. Further, the specification identifies SEQ ID NO:1-10 as subsequences for the 20q13 region. One would reasonably conclude that these subsequences are comprised within the RMC20C001 cosmid probe as it has been disclosed by Tanner et al to contain the region which is amplified in the genomic sequences of breast cancer patients.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

March 21, 2003